

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF GEORGIA  
SAVANNAH DIVISION**

GLORIA SMITH, )  
                        )  
Plaintiff,         )  
                        )  
v.                     )                   CV420-286  
                        )  
UNITED STATES OF     )  
AMERICA,             )  
                        )  
Defendants.         )

**ORDER AND REPORT AND RECOMMENDATION**

Gloria Smith filed this medical malpractice action against the United States and Dr. Kennedy Okere alleging that Dr. Okere, while treating Smith at Curtis V. Cooper Primary Health Center (“CVC”), prescribed her medicine to which she is allergic. Doc. 14 at 3. The United States moved to substitute as the sole defendant under the Federal Tort Claims Act (FTCA) and the Federal Employees Liability Reform and Tort Compensation Act of 1988 (the Westfall Act), doc. 17, which the Court granted, doc. 31.

The United States has moved to exclude certain causation testimony from four of Plaintiff's expert witnesses, and for summary judgment should the experts' testimony be excluded. Doc. 35. Plaintiff

responded, docs. 37 & 38, and submitted an updated affidavit from one of the challenged experts, doc. 38-1 at 1-4. The United States moved to strike the new affidavit, doc. 40, and replied in support of its motion to exclude and motion for summary judgment, doc. 41. Plaintiff sur-replied in opposition to the motions to exclude and for summary judgment, doc. 43, and responded to the motion to strike her expert's affidavit, doc. 44. The United States replied in support of its motion to strike, doc. 45, and sur-replied in support of its motion to exclude and for summary judgment, doc. 46. These motions are all ripe for disposition.

## I. BACKGROUND

Plaintiff Gloria Smith visited Curtis V. Cooper Primary Health Care (“CVC”) on December 5, 2018, where she treated with Dr. Kennedy Okere. *See* doc. 37 at 1. Dr. Okere prescribed her lisinopril-hydrochlorothiazide, which she filled and began taking that same day. *Id.* at 2. The prescribed medication contains an ACE inhibitor, and Smith is allergic to ACE inhibitors. *Id.* On April 8, 2019, Smith began feeling symptoms of angioedema and went to the hospital. *Id.* She remained in the hospital for two weeks. *Id.* at 3. Plaintiff claims her angioedema was caused by an allergic reaction to the medication. Doc. 14 at 3.

Plaintiff's Amended Complaint alleges professional negligence and simple negligence against the United States, through CVC, and against Dr. Okere for prescribing her medication to which she was allergic. Doc. 14. As explained above, the United States substituted in as the sole defendant in the case, and Dr. Okere was dismissed. Doc. 17. The Amended Complaint includes an affidavit from Dr. James Cornwell, pursuant to O.C.G.A. § 9-11-9.1, to support the malpractice claims. *See* doc. 14-1. Plaintiff also disclosed Dr. Cornwell as a retained expert pursuant to Federal Rule of Civil Procedure 26(a)(2)(B) and provided a copy of his expert report. Doc. 33 at 1, 5-10. Additionally, Plaintiff disclosed her treating physicians, Dr. Brad Rawlings, Dr. Gifford Lorenz, and Dr. Masood Ahmed, pursuant to Rule 26(a)(2)(C). *Id.* at 1-2. Her treating physicians did not submit reports. *See generally id.*

The United States has moved to exclude any causation opinions from Plaintiff's treating physicians on procedural grounds, doc. 35 at 3-6, and to exclude Dr. Cornwell's causation opinion based on Rule 702 of the Federal Rules of Evidence and the Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), *id.* at 6-11. It also seeks summary judgment, arguing that without the experts'

testimony as to causation, Plaintiff cannot carry her burden on her claims. *Id.* at 11-17.

In response, Plaintiff concedes that her treating physicians may not testify as to causation, doc. 38 at 3, but opposes exclusion of Dr. Cornwell's causation opinion, *id.* at 3-10. She also opposes summary judgment. *Id.* at 11-12. In that response, Plaintiff provided a supplemental affidavit from Dr. Cornwell. See doc. 38-1 at 1-4. The United States moves to strike this supplemental affidavit as untimely, doc. 40, but also argues that exclusion of Cornwell's causation testimony is appropriate even if the new affidavit is considered, doc. 41.

## II. ANALYSIS

### A. Plaintiff's Treating Physicians

Plaintiff's Expert Disclosure indicates that her treating physicians will testify about their "treatment, evaluation, and care of Plaintiff." Doc. 33 at 1-3. It also suggests that each of the three treating physicians "may also testify regarding causation." *Id.* As the Expert Disclosure makes clear, the treating physicians are offered under Federal Rule of Civil Procedure 26(a)(2)(C). *Id.* They did not provide reports. *Id.*

Generally, a Rule 26(a)(2)(C) expert, like a treating physician, is not required to provide an expert report. *See Fed. R. Civ. P. 26(a)(2)(C); Martin v. Wal-Mart Stores East, L.P.*, 2020 WL 5949222, \*2 (S.D. Ga. Oct. 7, 2020) (“Generally, treating physicians are not required to submit expert reports under Rule 26(a)(2)(B).”). However, where the treating physician plans to provide expert testimony as to causation, a Rule 26(a)(2)(B) report is often required. *Martin*, 2020 WL 5949222, at \*2. Therefore, the United States seeks to preclude the treating physicians from testifying as to causation. Doc. 35 at 6.

Plaintiff does not oppose this relief, and “clarifies that she does not seek to elicit testimony regarding causation from these witnesses.” Doc. 38 at 3. She further states that she “has no objection to Drs. Rawlings, Lorenz, and Ahmed being restricted from testifying to causation.” *Id.* The United States’ Motion to Exclude is, therefore, **GRANTED, in part.** Doc. 35.

### **B. Dr. Cornwell’s Causation Opinion**

Dr. Cornwell was identified by Plaintiff as a retained expert, and he submitted an expert report pursuant to Federal Rule of Civil Procedure 26(a)(2)(B). *See* doc. 33. As Plaintiff explains, Dr. Cornwell’s

report identifies two main opinions: (1) that Dr. Okere and CVC's prescribing of Lisinopril-HCT to Plaintiff violated the standard of care; and (2) that the prescription caused Plaintiff to suffer an adverse reaction, including angioedema. Doc. 38 at 3 (citing doc. 33 at 8); *see also* doc. 35 at 6. The United States moves to exclude only the second opinion, arguing that Dr. Cornwell is not qualified to opine on the cause of Plaintiff's angioedema and that the causation opinion is not based on any reliable methodology and would not assist the trier of fact. Doc. 35 at 6, 9-11.

Federal Rule of Evidence 702 compels the Court to act as a "gatekeeper" for expert evidence. *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) (citing *Daubert*, 509 U.S. at 589 n. 7, 597). In performing this task, the Court must consider whether the party offering the evidence has shown:

- (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

*Frazier*, 387 F.3d at 1260 (quoting *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir.1998)). The proponent of the expert opinion bears the burden of establishing qualification, reliability, and helpfulness by a preponderance of the evidence. *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1306 (11th Cir. 1999) (citing *Daubert*, 509 U.S. at 592 n.10).

Under the first prong, “experts may be qualified in various ways. While scientific training or education may provide possible means to qualify, experience in a field may offer another path to expert status.” *Frazier*, 387 F.3d at 1260–61; *see also* Fed. R. Evid. 702 (a witness may be qualified as an expert by “knowledge, skill, experience, training, or education[.]”). But, “[w]hen an expert witness relies mainly on experience to show he is qualified to testify, ‘the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.’” *Payne v. C.R. Bard, Inc.*, 606 F. App'x 940, 942-43 (11th Cir. 2015.) (quoting *Frazier*, 387 F.3d at 1261).

As to the second prong, the reliability “criterion remains a discrete, independent, and important requirement for admissibility.” *Frazier*, 387

F.3d at 1261. “The Supreme Court in *Daubert* set out a list of ‘general observations’ for determining whether expert testimony is sufficiently reliable to be admitted under Rule 702.” *United States v. Brown*, 415 F.3d 1257, 1267 (11th Cir. 2005) (citation omitted). These factors, or observations, inquire into the expert’s “theory or technique” and are: “(1) whether it can be (and has been) tested; (2) whether it has been subjected to peer review and publication; (3) what its known or potential rate of error is, and whether standards controlling its operation exist; and (4) whether it is generally accepted in the field.” *Id.* (citation omitted). “Sometimes the specific *Daubert* factors will aid in determining reliability; sometimes other questions may be more useful.” *Frazier*, 387 F.3d at 1262. “Indeed, the Committee Note to the 2000 Amendments of Rule 702 expressly says that, ‘[i]f the witness is relying solely or primarily on experience, then the witness must explain *how* that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.’” *Id.* at 1261.

Lastly, expert testimony must assist the trier of fact. *Frazier*, 387 F.3d at 1262. “By this requirement, expert testimony is admissible if it

concerns matters that are beyond the understanding of the average lay person.” *Id.* (citation omitted). This inquiry is commonly called the “helpfulness” inquiry. *Prosper v. Martin*, 989 F.3d 1242, 1249 (11th Cir. 2021) (citing *Frazier*, 387 F.3d at 1260). “Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *Id.* (quoting *Daubert*, 509 U.S. at 591).

Dr. Cornwell’s expert report explains that he is a “physician licensed to practice medicine in the state of Georgia, and [is] Board Certified in Family Medicine.” Doc. 33 at 5. He has been a practicing primary-care physician for 20 years, and has “substantial experience with treating hypertension, as well as the plethora of other medical conditions routinely encountered in primary care.” *Id.* In formulating his opinions in this case, he reviewed Plaintiff’s records from CVC, Candler Hospital, and CVS Pharmacy, along with four publications. *Id.*

Dr. Cornwell’s report details his opinion that Dr. Okere and CVC breached the applicable standard of care by prescribing an ACE inhibitor

to the Plaintiff.<sup>1</sup> Doc. 33 at 7-8. It then offers his relatively straightforward causation opinion:

Within a reasonable degree of medical certainty, the aforementioned negligent acts and omissions of CVC and Dr. Okere caused Ms. Smith to suffer a severe, life-threatening adverse reaction, including angioedema, for which she required emergency medical care and hospitalization, during April 2019.

*Id.* at 8. Based on Dr Cornwell's report, the United States argues that he is not qualified to opine on the cause of Plaintiff's angioedema and that his conclusory opinion regarding causation is unreliable and would not assist the finder of fact. Doc. 35 at 10-11.

In her response to the United States' motion, Plaintiff attached a previously undisclosed affidavit from Dr. Cornwell. Doc. 38-1 at 1-4.<sup>2</sup> It

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<sup>1</sup> The United States "does not dispute the admissibility of Dr. Cornwell's opinion that Dr. Okere violated the standard of care." Doc. 35 at 6, n. 3.

<sup>2</sup> The United States argues that the supplemental affidavit is untimely and should not be considered. *See generally* docs. 40 & 45. Plaintiff contends that, although submitted after the expert report deadline, it comports with Rule 26 because it is "merely an expansion" of what the original expert report disclosed. Doc. 44 at 4. She argues, alternatively, that even if the supplemental affidavit is untimely its late disclosure is either harmless or substantially justified. *Id.* at 5-12.

The District Court for the Southern District of Florida recently discussed the standard for considering untimely disclosed expert testimony, "even when the late disclosure is designated as 'supplemental' reports." *Riley v. Tesla, Inc.*, \_\_\_ F. Supp. 3d \_\_\_, 2022 WL 1486905, at \*3 (S.D. Fla. May 11, 2022). Courts have "broad discretion" to exclude untimely disclosed expert testimony, and a party cannot use supplementation under Rule 26(e) "as a means to bolster a previously disclosed defective or problematic expert witness report." *Id.* The Court could, therefore,

expands on his experience, stating he has “worked with patients dealing with hypertension since 2001, many of whom have experienced angioedema due to allergies from ACE inhibitors.” *Id.* at 1. He has also “worked with geriatric patients, who are at greater risk of angioedema since 2001.” *Id.* He estimates that over the course of his career he has “managed an estimated 20-30 patients suffering from angioedema.” *Id.* at 1-2.

The portions of the supplemental affidavit relevant to Dr. Cornwell’s causation opinion appear to be as follows:

There is no separate specialized training or knowledge required in the medical field to properly diagnose angioedema. This allergic reaction presents through swelling of the face, lips, eyes and throat. It is well accepted and documented in the medical community that lisinopril can cause angioedema. 0.1-0.7% patients prescribed ACE inhibitors experience angioedema.

Based on my knowledge, experience, training, and review of the publications, angioedema is the second most common adverse reaction to ACE inhibitors, behind dry cough.

Based on my knowledge, experience, and review of publications, patients who take ACE inhibitors can

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refuse to consider Dr. Cornwell’s supplemental affidavit as untimely. Nevertheless, in its discretion, the Court considered the newly produced affidavit. Because Dr. Cornwell’s causation opinion is excludable, even considering the contents of the supplemental affidavit, the motion to strike is **DISMISSED**, as moot. Doc. 40.

experience the adverse effect of angioedema several months or even up to a year after being prescribed the medication.

. . .

Within a reasonable degree of medical certainty, Dr. Okere's negligent prescription of a medication containing ACE inhibitors, coupled with the failure to notify the pharmacy and failure to document any discussion with patient or pharmacy regarding the stoppage of the medication caused Ms. Smith to suffer from an allergic reaction and angioedema, which caused her to be hospitalized for two weeks and to be placed in a medically-induced coma.

It is my opinion, to a reasonable degree of medical certainty, that Ms. Smith's angioedema, which was diagnosed by the ED doctor on April 8, 2019, was caused by an allergic reaction to lisinopril.

Doc. 38-1 at 2-4 (paragraph numbers omitted). Relying on both the original expert report and the supplemental affidavit, Plaintiff argues that Dr. Cornwell is qualified to render his causation opinion, and that the opinion is reliable and helpful. Doc. 38 at 3-10; doc. 43 at 4-13. Although the United States moves to strike this affidavit, it also argues that, even if the affidavit is considered, exclusion is still appropriate. Doc. 41 at 3.

Even considering Dr. Cornwell's supplemental affidavit, the United States is correct that he is not qualified to offer the causation opinion and that the opinion is not reliable. As to his qualifications, “[a]lthough the

Eleventh Circuit has not held that physicians must have a specialty in the relevant field to qualify as an expert, the area of the witness's expertise must align with the subject matter of the witness's testimony.” *Thompson v. United States*, 2019 WL 149553, at \*4 (S.D. Ga. Jan. 9, 2019) (Baker, J.) (citing *United States v. Paul*, 175 F.3d 906, 912 (11th Cir. 1999) (excluding law professor's handwriting analysis testimony, even though the professor had written on the topic, because his relevant expertise as a lawyer “did not make him any more qualified to testify as an expert on handwriting analysis than a lay person who read the same articles”)). As this Court has explained, “[a] medical degree . . . does not qualify a physician to testify concerning *any* medical issue; a physician's expert testimony must stay within the ‘reasonable confines’ of his or her practice area. *Thompson*, 2019 WL 149553, at \*4 (citing *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10th Cir. 2001)).

Dr. Cornwell is a licensed family-practice physician with twenty years of experience. See doc. 33 at 5. During that time, he has worked with patients dealing with hypertension, including patients who have experienced angioedema due to allergies from ACE inhibitors. Doc. 38-1 at 1. He has also worked with geriatric patients, who he indicates are at

greater risk of angioedema. *Id.* He estimates that over the course of his career he has “managed an estimated 20-30 patients suffering from angioedema.” *Id.* at 1-2. It appears that Dr. Cornwell might be qualified to opine on treating or managing patients with angioedema. However, expertise in the diagnosis and treatment of a condition does not render a physician qualified to opine, in a “scientifically reliable manner,” about the causes of those medical conditions. *Thompson*, 2019 WL 149553, at \*5 (quoting *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 673 (6th Cir. 2010)). Much like *Clarke v. Schofield*, “[t]his case does not involve questions of diagnosis; it involves a question of determining the etiology, the cause” of the Plaintiff’s angioedema. 632 F. Supp. 2d 1350, 1355 (M.D. Ga. July 9, 2009). “In other words, diagnosing a disease is not the same as determining the etiology of the disease.” *Id.* at 1358. Nothing in Plaintiff’s submissions show any training or experience in determining the cause of angioedema; instead, Dr. Cornwell’s own affidavit reveals that his experience, at best, includes diagnosing and treating patients suffering from angioedema. Doc. 38-1 at 1-2.

Plaintiff suggests that Dr. Cornwell’s lack of specialization in “angioedema or immunology” is overcome by his ability to testify about

studies done on angioedema. Doc. 38 at 7-8. Dr. Cornwell can remedy any defect in his experience, says Plaintiff, because the experience he does have allows him to “read, understand, and apply numerous medical journal studies to facts presented by Plaintiff’s medical records.” *Id.* at 7. However, while an expert may rely on other experts’ data in forming his own opinion, he may not use another expert’s report as “substantive evidence of one of his ultimate conclusions . . . .” *Deutz Corp. v. City Light & Power, Inc.*, 2009 WL 2986415, at \*6 (N.D. Ga. Mar. 21, 2009). “[A] person does not become an expert simply by reviewing an expert’s reports or research.” *Id.* (quoting *Larson v. Kempker*, 414 F.3d 936, 941 (8<sup>th</sup> Cir. 2005) (parenthetical)). Pointing to other potentially relevant studies on the topic is insufficient for Plaintiff to carry her burden of demonstrating that Dr. Cornwell is qualified to render his causation opinion. *See Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1292 (11th Cir. 2005) (“The party offering the expert has the burden of satisfying each of these three elements by a preponderance of the evidence.”).

Plaintiff also fails to carry her burden of demonstrating that Dr. Cornwell’s methodology is reliable. The initial report provides the conclusory opinion that Dr. Okere’s prescribing lisinopril to Plaintiff

caused her angioedema. Doc. 33 at 8. While it identifies “[p]ertinent [p]oints” from four publications, including data about the risk of ACE inhibitor-induced angioedema, it does not offer any explanation of how Dr. Cornwell arrived at his conclusion that Plaintiff’s April 2019 episode of angioedema was caused by the ACE inhibitor medication. *Id.* at 6-8. His supplemental affidavit does not offer much more in the way of methodology, instead only reiterating that “lisinopril can cause angioedema,” that “0.1-0.7% patients prescribed ACE inhibitors experience angioedema,” that “angioedema is the second most common adverse reaction to ACE inhibitors, behind dry cough,” and that “patients who take ACE inhibitors can experience the adverse effect of angioedema several months or even up to a year after being prescribed the medication.” Doc. 38-1 at 2. He also notes that he works with geriatric patients, who are “at a greater risk of angioedema.” *Id.* at 1. None of these observations explain how Dr. Cornwell arrived at his conclusion that lisinopril caused Plaintiff’s specific case of angioedema. *Id.*

Plaintiff’s brief in response to the motion to exclude highlights the issue with the reliability of Dr. Cornwell’s causation opinion. As she frames it:

In forming his causation opinion in this case, Dr. Cornwell began by reviewing pertinent medical literature regarding angioedema and ACE inhibitors, establishing a link between Plaintiff's Lisinopril ingestion and her angioedema and adverse reaction. [Cit.] According to the peer-reviewed literature Dr. Cornwell studied[,] Lisinopril is an ACE inhibitor which can induce angioedema in users which can occur even after years of stable therapeutic use. [Cit.] In reviewing Plaintiff's medical records Dr. Cornwell documented instances where Plaintiff's ACE inhibitor allergy was noted, with several also indicating angioedema as Plaintiff's allergic/adverse reactions to ACE inhibitors, instances where Plaintiff was admitted to the hospital with angioedema induced by Lisinopril, and instances where Lisinopril was prescribed to Plaintiff. [Cit.] After reviewing the pertinent medical literature and analyzing a decade of Plaintiff's medical history . . . , Dr. Cornwell drew upon his 20 years of medical knowledge and experience and reached the conclusion that the negligent acts of Dr. Okere in prescribing Lisinopril to Plaintiff caused Plaintiff to suffer a severe, life threatening adverse reaction, including angioedema, a reaction she had suffered due to Lisinopril in the past.

Doc. 38 at 8. Broken down to its component parts, Dr. Cornwell's methodology included (1) reviewing peer-reviewed articles that conclude angioedema is a potential risk from taking ACE inhibitors; (2) reviewing Plaintiff's medical records which include documentations that she is allergic to ACE inhibitors and has suffered from angioedema in the past, purportedly as a result of taking medication containing ACE inhibitors; and (3) drawing from his "20 years of medical knowledge and experience."

*Id.*

Identifying lisinopril as a potential cause of Plaintiff's angioedema and suggesting that her angioedema was therefore caused by her ingestion of the medication based on the order in which the events occurred, is not sufficient. *Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245, 1254 (11th Cir. 2010) ("Temporal proximity is generally not a reliable indicator of a causal relationship."). In the context of a pharmaceutical products liability case, *McClain v. Metabolife Intern., Inc.*, 401 F.3d 1233, 1242-43 (11th Cir. 2005), the Eleventh Circuit reversed a trial court's decision to admit a challenged expert's testimony and highlighted some of the same issues with that expert's opinion that exist here. It discussed the "*post hoc ergo propter hoc* fallacy[, which] assumes causality from temporal sequence," and explained "simply because a person takes drugs and then suffers an injury does not show causation." *Id.* at 1243.

Dr. Cornwell looks to the Plaintiff's medical records, which reveal prior episodes of angioedema, to support his conclusion that the lisinopril must have caused the relevant episode. Review of medical records "is not alone sufficient to demonstrate a reliable methodology." *Stewart v. Johnson*, 2021 WL 3030174, at \*4 (S.D. Ga. July 19, 2021). And Dr.

Cornwell's reliance on his medical knowledge and experience—notwithstanding the determination above that he is unqualified—“does not provide a sufficient foundation rendering the opinions [he] expresses reliable.” *Id.* When an expert is relying on experience, he must “explain how his experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion and how that experience is reliably applied to the facts.” *Frazier*, 387 F.3d at 1261 (quotation marks, citation, and emphasis omitted). Other than referencing his treatment of patients suffering from angioedema, Dr. Cornwell offers no explanation of how his experience was applied to the facts of Plaintiff's case to determine the cause of her angioedema. *See* docs. 33 & 38-1.

Plaintiff cites to *McKay v. Novartis Pharmaceuticals Corp.*, 984 F. Supp. 2d 647, 653 (W.D. Tex. 2012), as support for her claim that Dr. Cornwell's methodology is reliable. Doc. 38 at 9. There, the Western District of Texas found an expert's reliance on his own observations from practice, along with his review of publications addressing the association between certain medications and the plaintiff's medical condition, to be reliable for purposes of general causation—that is, the expert could testify generally that the medication could cause the condition. 984 F.

Supp. 2d. at 653. However, for purposes of specific causation—whether the medication caused the plaintiff's condition in particular—the court analyzed the expert's “differential diagnosis.” *Id.* at 655. Because the expert ruled out other possible causes of the plaintiff's medical condition, the expert's opinion that the medication caused the plaintiff's particular condition was considered reliable and admissible. *Id.* Another case relied upon by Plaintiff, *Southern States Coop., Inc. v. Melick Aquafeeds, Inc.*, 701 F. Supp. 2d 1348, 1358-59 (M.D. Ga. 2010), also explores the admissibility of an expert's differential diagnosis methodology in opining on the cause of a medical condition.

Differential diagnosis is “a scientific technique where the expert identifies the cause of a medical problem by ‘eliminating the likely causes until the most probable one is isolated.’” *Longoria v. Ethicon, Inc.*, 2020 WL 7238151, at \*2 (M.D. Fla. Dec. 9, 2020) (quoting *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 602 (S.D.W. Va. 2013)). “When properly conducted, a differential diagnosis can be a reliable methodology under *Daubert*.” *Guinn*, 602 F.3d at 1253. It “need not rule out all possible alternative causes[.]” *Id.* “The alternative causes . . . affect the weight that the jury should give the expert's testimony and not the admissibility of that

testimony[.]” *Katsiasfas v. C. R. Bard, Inc.*, 2020 WL 1808895, at \*2 (M.D. Fla. Apr. 9, 2020) (internal quotations and citation omitted). “However, a ‘differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation.’” *Dotson v. Am. Med. Sys., Inc.*, 2020 WL 2844738, at \*3 (N.D. Ga. Mar. 11, 2020) (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 265 (4th Cir. 1999)); *see also Katsiasfas*, 2020 WL 1808895, at \*2 (differential etiology is not reliable if “the expert is unable to offer any explanation for his or her causation opinion in light of the alternative causes offered by the opposing party.”).

Even though Plaintiff cites to cases where courts have analyzed the reliability and admissibility of differential diagnosis opinions, there is nothing to suggest that Dr. Cornwell undertook such a process here. He relies on publications that discuss the “vast” possible causes of angioedema, *see doc. 38-1 at 73*, yet he does not discuss any of these other possible causes of Plaintiff’s angioedema. *See generally docs 33; 38-1*. Dr. Cornwell’s failure to even *consider* other factors that could have been the cause of Plaintiff’s angioedema renders his methodology unreliable. *Guinn*, 602 F.3d at 1254 (“The district court did not abuse its discretion

in finding that [the expert's] differential diagnosis was unreliable under *Daubert* because she failed to adequately consider possible alternative causes of [Plaintiff's medical conditions]."). Indeed, the Eleventh Circuit has cautioned that “[a] reliable methodology should take into account the background risk.” *McClain*, 401 F.3d at 1243. The “background risk” does not mean the risk posed by the Lisinopril at issue; instead, it is “the risk a plaintiff and other members of the general public have of suffering the disease or injury that plaintiff alleges *without* exposure to the drug . . . in question.” *Id.* Dr. Cornwell did not identify any other potential causes of angioedema, though his materials indicate they do exist. *See generally* docs. 33 & 38-1; *see also* doc. 38-1 at 73. His failure to “meaningfully address other potential causes of [Plaintiff's] conditions or even the background risk of those conditions” is a “fundamental methodological failure.” *Williams v. Mosaic Fertilizer, LLC*, 889 F.3d 1239, 1250 (11<sup>th</sup> Cir. 2018). Like the expert in *Everett v. Georgia-Pacific Corp.*, 949 F. Supp. 856 (S.D. Ga. 1996), Dr. Cornwell “failed to engage in any rigorous analysis to determine the cause of [Plaintiff's] illness.” *Id.*

at 858 (emphasis added).<sup>3</sup> Plaintiff has failed to carry her burden of demonstrating the reliability of Dr. Cornwell's methodology. *Rink*, 400 F.3d at 1292.

For the foregoing reasons, the United States' Motion to Exclude the causation opinion of Dr. Cornwell is **GRANTED**.<sup>4</sup> Doc. 35, in part.

### C. Summary Judgment

The United States also moves for summary judgment, doc. 35 at 11-17, which Plaintiff opposes, doc. 38 at 11-12; *see also* doc. 43 at 13-15. Summary judgment "shall" be granted if "the movant shows that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A fact is 'material' if it 'might affect the outcome of the suit under the governing law.'"

*FindWhat Inv'r Grp. v. FindWhat.com*, 658 F.3d 1282, 1307 (11th Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)).

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<sup>3</sup> For example, the challenged expert in *Everett* admitted that he did not eliminate other potential causes of the Plaintiff's illnesses before offering his theory of causation. 949 F. Supp. at 859.

<sup>4</sup> The United States also argues that Dr. Cornwell's causation opinion would not assist the trier of fact. *See* doc. 35 at 11. Because the Court excludes the opinion based on qualification and reliability, it need not reach this third argument.

A dispute is “genuine” if the “evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Id.*

The moving party bears the burden of establishing that there is no genuine dispute as to any material fact and that it is entitled to judgment as a matter of law. *See Williamson Oil Co. v. Philip Morris USA*, 346 F.3d 1287, 1298 (11th Cir. 2003). Specifically, the moving party must identify the portions of the record which establish that “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” *Moton v. Cowart*, 631 F.3d 1337, 1341 (11th Cir. 2011) (quoting Fed. R. Civ. P. 56(a)). When the nonmoving party would have the burden of proof at trial, the moving party may discharge his burden by showing that the record lacks evidence to support the nonmoving party's case or that the nonmoving party would be unable to prove his case at trial. *See id.* (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986)).

If the moving party discharges his burden, the burden shifts to the nonmovant to go beyond the pleadings and present affirmative evidence to show that a genuine issue of fact does exist. *Anderson*, 477 U.S. at 257. Where the nonmovant attempts to carry this burden with nothing

more “than a repetition of his conclusional allegations, summary judgment for the [movant is] not only proper but required.” *Morris v. Ross*, 663 F.2d 1032, 1033-34 (11th Cir. 1981); *see also Eberhardt v. Waters*, 901 F.2d 1578, 1580 (11th Cir.1990) (“A party opposing a properly submitted motion for summary judgment may not rest upon mere allegations or denials of his pleadings, but must set forth specific facts showing that there is a genuine issue for trial.”). “There is no genuine issue of material fact if the nonmoving party fails to make a showing sufficient to establish the existence of an element essential to that party's case and on which the party will bear the burden of proof at trial.” *Jones v. Gerwens*, 874 F.2d 1534, 1538 (11th Cir.1989).

In determining whether a summary judgment motion should be granted, a court must view the record and all reasonable inferences that can be drawn from the record in the light most favorable to the nonmoving party. *Peek-A-Boo Lounge of Bradenton, Inc. v. Manatee County*, 630 F.3d 1346, 1353 (11th Cir. 2011) (citing *Rodriguez v. Sec'y for Dep't of Corr.*, 508 F.3d 611, 616 (11th Cir. 2007)). However, “facts must be viewed in the light most favorable to the non-moving party only if there is a ‘genuine’ dispute as to those facts.” *Scott v. Harris*, 550 U.S.

372, 380 (2007) (quoting Fed. R. Civ. P. 56(c)). “[T]he mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact.” *Id.* (emphasis and citations omitted).

Plaintiff’s case is brought under the FTCA. “Liability in an FTCA action is determined in accordance with the law of the place where the government’s act or omission occurred . . . .” *Stevens v. Battelle Mem'l Inst.*, 488 F.3d 896, 899 n.3 (11th Cir. 2007) (citing *Cole v. United States*, 755 F.2d 873, 879 n.16 (11th Cir. 1985) and 28 U.S.C. § 1346(b)). Because the alleged negligent acts occurred in Georgia, Georgia law applies.

“To prove a medical malpractice claim in Georgia, a plaintiff must show: (1) the duty inherent in the health care provider-patient relationship; (2) breach of that duty by failing to exercise the requisite degree of skill and care; and (3) that this failure is the proximate cause of the injury sustained.” *Knight v. W. Paces Ferry Hosp., Inc.*, 585 S.E.2d 104, 105 (Ga. Ct. App. 2003) (citing *Zwieren v. Thompson*, 578 S.E.2d 862, 864 (Ga. 2003)). To recover, a plaintiff must show not only a violation of the applicable medical standard of care but also that the purported

violation is the proximate cause of the injury sustained. *Allen v. Fam. Med. Ctr., P.C.*, 652 S.E.2d 173, 175 (Ga. Ct. App. 2007) (citation and quotes omitted). “Proof of negligence, alone, is insufficient to sustain recovery.” *Id.*

To establish proximate cause, a plaintiff must present expert testimony to establish that the breach of the applicable standard of care was the proximate cause of the relevant injury. *See Dutton v. United States*, 2018 WL 4259250, at \*2 (S.D. Ga. Sept. 6, 2018) (citing *Porter v. Guill*, 681 S.E.2d 230, 235 (Ga. Ct. App. 2009)); *see also Zwiren*, 578 S.E.2d at 865 (“In order to establish proximate cause by a preponderance of the evidence in a medical malpractice action, the plaintiff must use expert testimony because the question of whether the alleged professional negligence caused the plaintiff’s injury is generally one for specialized expert knowledge beyond the ken of the average layperson.” (citations omitted)); *Allen*, 652 S.E.2d at 175 (explaining requirement that proximate cause in medical malpractice cases be established using expert testimony). Even in simple negligence cases, “where a ‘medical question’ involving truly *specialized* medical knowledge (rather than the sort of medical knowledge that is within common understanding and

experience) is needed to establish a causal link between the defendant's conduct and the plaintiff's injury." *Cowart v. Widener*, 697 S.E.2d 779, 781 (Ga. 2010). The Eleventh Circuit has recognized that a plaintiff who fails to present credible expert testimony to support causation are "unable to establish a prima facie case of medical malpractice" under Georgia law. *Eley v. Baptist Hosp. Worth Cty., Inc.*, 199 F. App'x 757, 758 (11th Cir. 2006).

The United States argues that, without the expert testimony excluded above, Plaintiff cannot establish the causation element of her negligence claim. Doc. 35 at 17. In response, Plaintiff first focuses on the merits of the motion to exclude, arguing Dr. Cornwell's causation testimony is admissible and she has therefore "produced expert medical testimony based on 'reasonable medical probability' that Dr. Okere's negligent prescription of lisinopril and Plaintiff's ingestion of the medication to her severe angioedema and hospitalization [sic]." Doc. 38 at 11; doc. 43 at 14-15. However, the Court's analysis above forecloses that argument; the expert causation testimony is excluded.

Plaintiff next argues, in a rather conclusory fashion, that "expert testimony is not the sole method for Plaintiff to offer proof of causation."

*Id.* She points to her own deposition, scholarly publications, and lay testimony as “additional evidence” which she contends supports “an inference of causation.” *Id.* The Georgia case law discussed above seems to foreclose that argument, too. In support of her contention, Plaintiff cites to a breast implant products liability case, *Allison v. McGhan Medical Corp.*, 184 F.3d 1300 (11th Cir. 1999), where the Eleventh Circuit did recognize that Georgia law permits a plaintiff to “present medical as well as non-medical evidence to show causation.” *Id.* at 1320. However, it also reiterated that “medical expert testimony *was essential* to prove causation” because whether the breast implants could and did cause the Plaintiff’s disease “is not a natural inference that a juror could make through human experience.” *Id.* (emphasis added). So too, here. Plaintiff’s sur-reply appears to concede this issue. See doc. 43 at 14 (“As Defendant has pointed out, this is a case where ‘the existence of a causal link between the defendant’s conduct and the plaintiff’s injury cannot be determined from common knowledge and experience’ and so requires the ‘assistance of experts with specialized medical knowledge.’” (quoting *Cowart*, 697 S.E.2d at 784)).

Finally, Plaintiff attempts to turn her burden on its head, arguing “Defendant is the party that has failed to disclose any expert witness that opines that the lisinopril prescription did not cause Plaintiff’s angioedema in April 2019.” Doc. 43 at 14. In doing so, she misunderstands the standard for summary judgment, if not civil liability generally. The Georgia Supreme Court has categorized Plaintiff’s burden as “clear”: she “cannot recover for medical malpractice, even where there is evidence of negligence, unless [she] establishes by a preponderance of the evidence that the negligence either proximately caused or contributed to cause plaintiff harm.” *Zwiren*, 578 S.E.2d at 864 (internal cites, quotation, and alteration omitted). To do so, she *must* use expert testimony. *Id.* at 865. It does not matter, for purposes of the motion for summary judgment, that the United States has no expert witness. “There is no genuine issue of material fact if the nonmoving party fails to make a showing sufficient to establish the existence of an element essential to that party’s case and on which the party will bear the burden of proof at trial.” *Jones*, 874 F.2d at 1538.

Georgia law is clear—proximate cause in a medical negligence case requires expert testimony. *See, e.g., Dutton*, 2018 WL 4259250, at \*5

(granting summary judgment in FTCA medical malpractice action where plaintiff had no expert testimony establishing that defendant's negligence was the proximate cause of plaintiff's decedent's death); *Cowart*, 697 S.E.2d at 784 ("[P]laintiffs must come forward with expert evidence to survive a defense motion for summary judgment, where 'medical questions' relating to causation are involved."). The United States has discharged its burden on its motion by showing that the Plaintiff cannot prove proximate causation at trial. *Moton*, 631 F.3d at 1341. Therefore, its Motion for Summary Judgment should be **GRANTED**. Doc. 35, in part.

### III. CONCLUSION

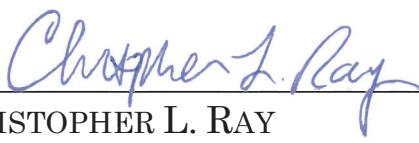
The United States' Motion to Exclude is **GRANTED**. Doc. 35, in part. Plaintiff's treating physicians are **EXCLUDED** from offering any opinion as to causation. Additionally, Dr. James Cornwell's opinion as to the cause of Plaintiff's angioedema is **EXCLUDED** under Federal Rule of Evidence 703. The United States' Motion for Summary Judgment should be **GRANTED**. Doc. 35, in part.

This Report and Recommendation (R&R) is submitted to the district court judge assigned to this action, pursuant to 28 U.S.C. §

636(b)(1)(B) and this Court's Local Rule 72.3. Within 14 days of service, any party may file written objections to this R&R with the Court and serve a copy on all parties. The document should be captioned "Objections to Magistrate Judge's Report and Recommendations." Any request for additional time to file objections should be filed with the Clerk for consideration by the assigned district judge.

After the objections period has ended, the Clerk shall submit this R&R together with any objections to the assigned district judge. The district judge will review the magistrate judge's findings and recommendations pursuant to 28 U.S.C. § 636(b)(1)(C). The parties are advised that failure to timely file objections will result in the waiver of rights on appeal. 11th Cir. R. 3-1; *see Symonette v. V.A. Leasing Corp.*, 648 F. App'x 787, 790 (11th Cir. 2016); *Mitchell v. United States*, 612 F. App'x 542, 545 (11th Cir. 2015).

**SO ORDERED AND REPORTED AND RECOMMENDED**, this 12th day of August, 2022.

  
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CHRISTOPHER L. RAY  
UNITED STATES MAGISTRATE JUDGE  
SOUTHERN DISTRICT OF GEORGIA